REMARKS

Claims 1, 3, 7-20, 22, and 37 are pending in the application. The claims have not been amended by the present response.

Allowable Claims

At pages 2 and 8, the Office Action stated that claims 3, 12, and 13 would be allowable if rewritten in independent format. In view of the remarks presented herein, applicant respectfully submits that all of the pending claims are in condition for allowance.

35 U.S.C. § 112, First Paragraph (Written Description)

At pages 2-8 of the Office Action, claims 1, 7-11, 14-20, 22, and 37 were rejected as allegedly containing subject matter that was not described in the specification in such a way that one skilled in the art can reasonably conclude that the inventor, at the time the application was filed, had possession of the claimed invention.

Independent claim 1 is directed to a method of identifying a candidate substance that inhibits aggregation of a mammalian aggregate-prone amyloid protein in a yeast cell. The claimed method includes the following steps: (a) contacting a yeast cell that expresses a chimeric protein comprising a mammalian aggregate-prone amyloid protein with a candidate substance under conditions effective to allow aggregated amyloid formation in the yeast cell; and (b) determining the ability of the candidate substance to inhibit the aggregation of the aggregate-prone amyloid protein in the yeast cell.

According to the Office Action,

> the specification fails to provide sufficient distinguishing identifying characteristics of the genus of "mammalian" proteins. There is no disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. The instant situation is directly analogous with the decision in University of California v. Eli Lilly and Co.

The Written Description Training Materials ("the Training Materials") published by the U.S. Patent and Trademark Office on March 25, 2008, provide helpful instruction for analyzing

the written description of a process claim where novelty resides in the process steps (see Example 16, at pages 55-56). As explained in Example 16 of the Training Materials, the sample claim analyzed therein relates to a novel method of introducing "a nucleic acid" into "mammalian cells." Although the specification describes the structure of only one nucleic acid (the beta-galactosidase gene) and reduces to practice only one species within the claimed genus, the sample process claim nonetheless satisfies the written description requirement because one of ordinary skill in the art would recognize the inventor to have been in possession of the claimed method at the time of filing. The Training Materials clearly explain that in certain contexts generic terms such as "nucleic acid" and "mammalian cells" can be used in a claim and satisfy the written description requirement.

Applicant strongly contests the assertion that the claims at issue in this application are analogous to those invalidated in Lilly. Lilly contained claims to novel DNA sequences. The claims of the present application are not directed to nucleic acids, proteins, or any other composition. Instead, the present application contains claims to screening methods. The claimed screening methods employ yeast cells for identifying a substance that inhibits the aggregation of a mammalian aggregate-prone amyloid protein. The present application describes prion protein (PrP) and β-amyloid as two examples of mammalian aggregate-prone amyloid proteins. As detailed in the response to the previous office action, the person of ordinary skill at the time the application was filed was aware that numerous other proteins are also able to form amyloid or amyloid-like deposits. The person of ordinary skill in the art would understand these well-characterized amyloid-forming proteins, including huntingtin, atrophin-1, ataxins, androgen receptor, tau, and α-synuclein, to be encompassed by the generic claim term "mammalian aggregate-prone amyloid protein." The term "mammalian" merely requires that the "aggregate-prone amyloid protein" be mammalian in origin. The skilled biologist would have no difficulty determining whether or not a given aggregate-prone amyloid protein is "mammalian" in origin.

The claims of the present application are generally analogous to the process claim of Example 16 of the Training Materials. The present claims are directed to screening methods that use a type of protein (compare Example 16, which exemplifies a claim to a process that uses "a nucleic acid" and "mammalian cells"). The pending claims are not to the protein itself (at the top of page 4, the Office Action incorrectly refers to "the claimed product" when asserting that

the present claims are like those of Lilly). In such a case, where the novelty of the claim resides in the process steps, rather than in the protein used in the process, one of ordinary skill in the art would recognize the inventor to have been in possession of the claimed method at the time of filing. As a result, applicant requests that the rejection be withdrawn.

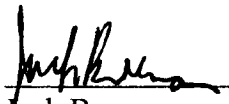
CONCLUSIONS

Applicant submits that all grounds for rejection have been overcome, and that all claims are in condition for allowance, which action is requested.

Enclosed is a Petition for Extension of Time. The extension of time fee is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 17481-004001.

Respectfully submitted,

Date: December 22, 2008



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